K002194

AUG 1 8 2000

VARIAN
medical systems

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Premarket Notification 510(k) Summary as required by 21 CFR 807.92

Date Summary was prepared:

July 14, 2000

Submitter's Name:

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Device Name:

TreatVision

Classification Name:

Medical Charged Particle Radiation Therapy Systems

Predicate Device:

VARiS 1.4g, K001643

Description of the Device

TreatVision is a member of the VARiS & Vision information and RV system product family.

VARiS & Vision is an information system designed to assist a Clinic in managing an Oncology practice. VARiS is composed of several applications. The basic applications are VARiS Clinic and VARiS Treatment. Optional applications include VARiS Simulation, VARiS Reports, VARiS Schedule, and VARiS Charges. The Vision product line for image management and planning includes Vision with optional applications like PortalVision, XimaVision, ScanVision, SomaVision, BrachyVision, ProtonVision and the **TreatVision**. Connectivity with external applications may be accomplished using the optional VARiS Link module.

The VARiS Clinic application provides the foundation for the VARiS information system. It includes the tools necessary to manage the radiotherapy department's clinical and business information. It includes Patient Registration, used to enter and review patient demographic data; Patient Chart, used to enter and review patient clinical data; Mini-Schedule, used to schedule patient appointments on treatment and simulation machines for single & multiple days; Patient Check-In, used to indicate patient arrival for scheduled appointments; and Administration, used to handle system administration tasks.

The RT Treatment Record application provides data entry and review capabilities for radiotherapy related information. In particular it visualizes radiotherapy related data in terms of prescription, treatment plan and treatment record (history) and allows data entry and modification based on user rights.

The VARiS Treatment application provides a Record & Verify function designed to assist the operator of a radiation therapy device in providing accurate treatment setups for each patient by monitoring set up parameters and preventing the radiation therapy device from commencing irradiation while any parameter is out of conformance. It also provides for selecting patients from a queue provided by the schedule, retrieval of plans for the selected patient, evaluation of selected treatment plan to determine whether predefined dose limits will be exceeded, auto sequencing of fields for the selected patient, acquisition of positional data from radiation therapy devices, and overriding of treatment parameters based on user rights. It also records results of treatment delivery, including dose delivered to defined sites. For radiation therapy devices that incorporate internal treatment verification, the optional **TreatVision** provides management and record functions designed to assist the operator of radiation therapy devices with downloads of treatment plan parameters. It is based on the ACR/NEMA standard DICOM version 3 for data format and the communication protocol. It provides downloads of plan parameters and records the delivered treatments. It also provides for selecting patients from a queue provided by the schedule application, retrieval of plans for the selected patient, evaluation of selected treatment plan to determine whether predefined dose limits will be exceeded, auto sequencing of fields for the selected patient, and overriding of dose limits and break points based on user rights. It also records results of treatment delivery, including dose delivered to defined sites.

The optional VARiS Simulation application provides an interface to radiation therapy simulation devices. It provides for selecting patients from a queue provided by the schedule, monitoring radiation therapy simulation device setup parameters and acquisition of these setup parameters. It also allows the operator to create and modify simulation and treatment fields, and to associate simulation fields with a patient's chart record.

The optional VARiS Reports application provides predefined reports, viewed online or printed, covering a variety of topics useful in managing an Oncology practice. It also provides a report builder to allow a user to generate custom reports.

The optional VARiS Schedule application is a resource manager for oncologists, staff, machines and all

other oncology-related activities. It provides daily and monthly scheduling views, editing of these views, simple rescheduling of all resources related to an appointment, and patient & staff tracking by scheduled activity. It allows automatic scheduling of full courses of treatment, conflict resolution, task assignment, status and duration tracking for all activities.

The optional VARiS Charges application provides treatment-strategy templates to forecast and track treatment and administrative activities, posting of charges for completed activities, review of costs by categories, review using online screens and printed reports, and cost & charge export via Link.

The optional VARiS Link module provides an interface that allows a user to insert, retrieve and update data in VARiS database while maintaining data integrity, using SQL programming principles.

Vision is the core of all imaging applications, since it provides the integration of all data and images in one central database. All Vision workstations support the entry, visualization and management of all data and images stored in the system. Depending on the available system options, images can also be imported through the network using DICOM, the available image import filters or by means of film digitizers.

The optional PortalVision application provides electronic portal imaging capabilities. Within external radiation therapy, electronic portal images can be acquired before, during or after each fraction by use of PortalVision. PortalVision also supports double exposure and cine loop image acquisition. In addition, PortalVision provides tools for quantitative portal image registration and review by physicians.

The optional XimaVision application allows the live display of fluoroscopic images and the acquisition of them as simulation images, as well as the capture of the related geometrical parameters of the simulator. Distortions within the images are corrected automatically. Simulation fields are generated using the parameters from the Ximatron.

The optional ScanVision is a computed tomography acquisition system, for Varian Ximatron radiotherapy simulators. Therefore, it supports the acquisition and display of tomographic images, with the all image-processing tools known from the Vision environment.

The optional SomaVision is an application for physicians and other clinical professionals for 3D image viewing, segmentation, strategy planning and plan approval. It integrates treatment planning with the Vision applications and it provides connectivity to the CadPlan treatment planning system for dose calculation. With these planning capabilities, SomaVision frees CadPlan workstations for dose calculation and optimization.

The optional BrachyVision (formerly CadPlan BT) application integrates Brachytherapy planning within the Vision environment.

The optional ProtonVision application is used to plan proton radiation therapy treatments. It includes also tools for treatment preparation (diagnostic image analysis, contouring and segmentation) and plan review.

Intended Use:

The TreatVision RV function is designed to assist the operator of a self-verifying radiation therapy device in

providing accurate treatment setups for each patient. Additional applications provide various data management and library functions.

Technological Characteristics:

VARiS & Vision 7.0 is designed to run on PC servers running Microsoft® Windows NT Server or Microsoft® Windows 2000; and PC client workstations running Windows NT Workstation or Windows 2000. The VARiS & Vision 7.0 system runs on a Sybase version 11.9.2.1 database, and is accessed using Sybase Open Client version 11.1.1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2000

Linda Nash
Corporate Director, Regulatory Affairs
and Quality Assurance
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Palo Alto, CA 94304-1038

Re: K002194
TreatVision (Medical Charged Particle
Therapy System Accessory)
Dated: July 19, 2000
Received: July 20, 2000
Regulatory class: II
21 CFR 892.5050/Procode: 90 LHN

Dear Ms. Nash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

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510(k) Number: K002194

Device Name: TreatVision

Indication for Use

The TreatVision option to VARiS is used as an ancillary (or adjunct) device to assist the Radiation Therapist in reducing inaccuracies in setting up treatments to be delivered by a radiation therapy device. The indications for use include any disease or condition treatable with radiation therapy, including but not limited to cancer.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use___

(per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002194